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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/518,405 | 11/18/2005 | Motonori Miyakawa | Q85416 | 8028 |
| 23373 7590 01/10/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | | |
| | | | EXAMINER GALLIS, DAVID E | |
| | | | ART UNIT 1625 | PAPER NUMBER |
| | | | MAIL DATE 01/10/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/518,405 | MIYAKAWA ET AL. | |
| | Examiner | Art Unit | |
| | David E. Gallis | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1, 3-6, 11, and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/07 and 12/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1 through 6 and 11 and 12 are pending. Claims 6, 11, and 12 have been amended. Claim 2 has been withdrawn. Claims 7 through 10, and 13 have been cancelled. Applicants' claim to foreign priority from the National Stage of Application No. PCT/JP03/07799 filed June 19, 2003 is acknowledged. As such, all conditions pursuant to 35 U.S.C. 119(a-d) have been met for the foreign priority date of June 19, 2002 provided by application JP 179088/2002.

Prior Rejections

2. With respect to the provisional rejection of claims 1 and 3 through 6 on the basis of obviousness-type double patenting, applicants have filed a terminal disclaimer for application 10/552553 (filed January 27, 2005). Therefore the provisional rejection with regard to obviousness-type double patenting is hereby withdrawn.

3. With respect to the rejection of claims 11 through 13 on the ground of lacking enablement for "prevention" under 35 USC 112 first paragraph, applicants have cancelled claim 13 and amended the claims 11 and 12 to claim only treatment of the subject diseases. Therefore the rejection of claims 11 and 12 as lacking enablement is hereby withdrawn.

4. With respect to the rejection of claims 11 through 13 on the ground of lacking enablement for the claimed treatment of all diseases cited under 35 USC 112 first paragraph, applicants have cancelled claim 13 and amended the claims 11 and 12 to claim only treatment of osteoporosis, muscle wasting, and male hypogonadism.

Applicants arguments and supportive reference were found persuasive with regard to

treatment of these diseases. Therefore the rejection of claims 11 and 12 as lacking enablement for the claimed treatment of these conditions is hereby withdrawn.

5. With respect to the rejection of claims 11 through 13 under 35 USC 112 second paragraph on the ground of being indefinite, applicants' have canceled claim 13 and amended claims 11 and 12 to recite definite terminology and to define to condition of wasting disease. Therefore the rejection of claims 11 and 12 as being indefinite is hereby withdrawn.

Quayle Action

6. This application is in condition for allowance except for the following formal matters:

7. Claims 1, 3, 4, and 5 are objected to as containing non-elected subject matter, but would be allowable if rewritten to include all of the limitations with respect to the elected Group IV subject matter.

The functional group options of formula (I) that characterize the elected Group IV are as follows:

R¹ is a cyano group;
R² is hydrogen;
X is CH;
Y is -C(CH₃)₂-CH₂-;
Z is substituted or unsubstituted heteroaryl; and
m is 0.

The compounds of formula (I) that exemplify the elected Group IV are examples 100 through 112 of the instant disclosure. Subject matter in claims 1, 3, 4, and 5 that

does not read on the above elected Group IV subject matter must be removed from the claims.

Claims 6, 11, and 12 are objected to on the basis of their dependency on claims 1, 3, and 5.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

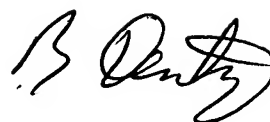
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis
Patent Examiner

A handwritten signature in black ink, appearing to read "B. Dentz", with a stylized flourish at the end.

BERNARD DENTZ
PRIMARY EXAMINER